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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,888	03/06/2002	Minoru Takebe	211A 3161 PCT	2747

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EXAMINER
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LI, QIAN JANICE

ART UNIT	PAPER NUMBER
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1633

DATE MAILED: 07/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b>	<b>Application No.</b> 10/070,888	<b>Applicant(s)</b> TAKEBE ET AL.	
	<b>Examiner</b> Q. Janice Li, M.D.	<b>Art Unit</b> 1632	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 29 June 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.  
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☒ The Notice of Appeal was filed on 29 April 2005. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
 (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);  
 (b) ☐ They raise the issue of new matter (see NOTE below);  
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
 5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.  
 6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
 The status of the claim(s) is (or will be) as follows:  
 Claim(s) allowed: \_\_\_\_\_  
 Claim(s) objected to: \_\_\_\_\_  
 Claim(s) rejected: 1-7,9-13, 15.  
 Claim(s) withdrawn from consideration: \_\_\_\_\_

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.  
 12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_  
 13. ☐ Other: \_\_\_\_\_

**Q. JANICE LI, M.D.**  
**PRIMARY EXAMINER**

Q. Janice Li, M.D.  
 Primary Examiner  
 Art Unit: 1632

Continuation of 3. NOTE: The proposed amendment, if being entered, would raise new issue under 35 U.S.C. § 112, 2nd paragraph, and requires further search and consideration.

Continuation of 5. Applicant's reply has overcome the following rejection(s): 35 U.S.C. 102(b) as being anticipated by Takebe et al (USP 5,885,632, USP 6,045,819, USP 6,303,161) because the disclosed isoflavone aglycone is not comprised of at least 70wt% daizein.

Continuation of 11. does NOT place the application in condition for allowance because: Claims 1-7, 9-13, and 15 stand rejected under 35 U.S.C. 112 first paragraph for new matter because the proposed amendments have not been entered.

Claims 1-7, 9-13, and 15 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, for reasons of record and following.

Applicants cited case law to argue that Applicant's application clearly teaches how to make and use the invention and therefore the enablement requirement is met thereby.

In response, the cited case law clearly requires "a specification disclosure which contains a teaching of the manner or process of making and using the invention IN TERMS WHICH CORRESPOND IN SCOPE TO THOSE USED IN DESCRIBING AND DEFINING THE SUBJECT MATTER SOUGHT TO BE PATENTED" (See cited *Fiers v. Revel*). In the instant case, the claims are drawn to a material that augment any feature of any type of somatic stem cells such as the nerve stem cells, which are known as difficult to propagate or non-regenerable at all, whereas the specification only provide a disclosure for slightly increased number of spleen cell colonies. Thus, the disclosure is not correspondent in scope to the claim. Marzocchi teaches "IN THE FIELD OF CHEMISTRY GENERALLY, THERE MAY BE TIMES WHEN WELL-KNOWN UNPREDICTABILITY OF CHEMICAL REACTIONS WILL ALONE BE ENOUGH TO CREATE REASONABLE DOUBT AS TO ACCURACY TO BROAD STATEMENT PUT FORWARD AS ENABLING SUPPORT FOR CLAIM; THIS WILL ESPECIALLY BE THE CASE WHERE STATEMENT IS, ON ITS FACE, CONTRARY TO GENERALLY ACCEPTED SCIENTIFIC PRINCIPLES, ETC" (In re Marzocchi and Horton, 169 USPQ 367 CCPA1971).

Accordingly, for reasons of record and supra, the rejection stands.

Claims 1-7, 9-13, and 15 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and following.

In the response, applicants reiterated several statements in the specification for "the stem-cell-augmenting activity", but except the one in the paragraph bridging pages 3 and 4, they do not teach which aspect of the stem cells being augmented, the size, the enzyme activity or the proliferation ability?. Again, MPEP states, Claims must, under modern claim practice, stand alone to define invention, and incorporation into claims by express reference to specification and/or drawings is not permitted except in very limited circumstances. For example, if the disclosure shows the cell proliferation has been augmented, the claim should reflect such property.

Claims 1-7, 9-13, and 15 stand rejected under 35 U.S.C. 102(b) as being anticipated by Kelly et al (USP 6,642,212), for reasons of record and following

In the response, applicants argue that except in the claims, the disclosed products in the cited patents do not contain 70% weight percentage of diadzein, thus, they do not anticipate the instant claims.

In reply, it is noted that the patented claims are an essential part of the disclosure, thus, for reasons of record, the rejection stands.